UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

GENEVA PHARMACEUTICALS TECHNOLOGY CORP. (as successor in interest to Invamed, Inc.), Plaintiff,	:	
-v-	:	98 Civ. 861 (DLC)
BARR LABORATORIES, INC., BRANTFORD CHEMICALS INC., BERNARD C. SHERMAN, APOTEX HOLDINGS INC., APOTEX INC., and SHERMAN DELAWARE, INC ., Defendants.	:	99 Civ. 3607(DLC) OPINION AND ORDER
APOTHECON INC., Plaintiff,	:	
-v-	:	
BARR LABORATORIES, INC., BRANTFORD CHEMICALS INC., BERNARD C. SHERMAN, APOTEX HOLDINGS INC., APOTEX INC. and SHERMAN DELAWARE, INC ., Defendants.	:	

Appearances:

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DENISE COTE, District Judge:

Defendants Barr Laboratories, Inc. ("Barr") and Brantford Chemicals Inc. ("Brantford") have moved to determine the scope of remand or, in the alternative, for relief from a judgment under Rule 60(b) 2, Fed. R. Civ. P., and for supplemental discovery and expert reports and to complete expert depositions. For the reasons stated on the record at a conference on August 23, 2005

and for the reasons set forth below, the motion to determine the scope of the remand is granted. In the light of that determination, the discovery motions are also granted.

BACKGROUND

This action was commenced on February 6, 1998, by the filing of a complaint by Geneva Pharmaceuticals Technology Corp., as successor to Invamed, Inc. ("Geneva") and Apothecon, Inc. ("Apothecon") (collectively, the "Plaintiffs") against Barr, Brantford, Bernard C. Sherman ("Sherman"), Apotex Holdings Inc., Apotex Inc. ("Apotex") and Sherman Delaware Inc. ("Sherman Delaware") (collectively, the "Defendants").

The complaint alleges violations of Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S.C. §§ 1 and 2 (2000), Section 7 of the Clayton Act, 15 U.S.C. § 18 (2000), and state law relating to joint ventures, all arising out of the competition between manufacturers of generic warfarin sodium. After discovery, the Defendants moved for partial summary judgment, which was granted on May 10, 2002 (the "May 10 Opinion"). By its opinion of October 18, 2004, the Court of Appeals reversed the grant of summary judgment dismissing the Sherman Act Secions 1 and 2 claims, affirmed the dismissal of the Clayton Act claim and reversed the ruling that Apothecon lacked standing to sue (the "October 18 Opinion"). The May 10 and October 18 Opinions describe the parties and the factual background of the litigation, and familiarity with them is assumed.

The definition of the relevant warfarin sodium tablet market has been at issue throughout these proceedings. Geneva and Apothecon alleged two relevant markets in their complaints: "generic warfarin sodium and/or branded and generic warfarin sodium." In their motion for summary judgment, the Defendants argued in part that the Plaintiffs could not carry their burden of proving a relevant market of "generic warfarin sodium" and that Barr could not possibly possess monopoly power in a relevant market of "branded and generic warfarin sodium." Plaintiffs opposed Defendants' motion for summary judgment, asserting that the definition of the relevant market raised disputed issues of fact.

The May 10 Opinion rejected Plaintiffs' generics-only market definition, holding in relevant part that "[t]he relevant product market is the combined group of generic and the branded warfarin sodium," and concluding that Barr could not possibly hold monopoly power in this market. Accordingly, it dismissed Plaintiffs' Section 2 claims relating to the warfarin sodium market. Geneva Pharms. Tech. Corp. v. Barr Labs., Inc., 201 F. Supp. 2d 236, 271 (S.D.N.Y. 2002). The May 10 Opinion entered summary judgment against Plaintiffs on their other antitrust claims as well.

With respect to the relevant market definition, the Plaintiffs argued on appeal that "the District Court erred in disregarding the evidence and making a factual finding on relevant market that should have been reserved for the jury."

In the October 18 Opinion, Geneva Pharms Tech. Corp. v. Barr Labs., Inc., 386 F.3d 485 (2d Cir. 2004), the Court of Appeals discussed the standard of review applied in summary judgment cases:

> We review a grant of summary judgment de novo to ensure the district court applied substantive antitrust law correctly. A grant of such relief is proper if there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Upon reviewing the record, we draw all inferences and resolve all ambiguities in favor of the non-moving party, here plaintiffs.

Id. at 495 (citation omitted).

Before analyzing the evidence, the Court of Appeals made the following statement:

> The district court ruled that the entire warfarin sodium market, including Coumadin, was the appropriate market. It had noted the chemical equivalence between Coumadin and generics, found that customers and vendors viewed the products as competing, and concluded that generics took market share from Coumadin. We have performed our own analysis of the Brown Shoe factors and we conclude to the contrary that in this case generics alone constitute the relevant market.

Id. at 496. The Court of Appeals considered the evidence cited by Plaintiffs in support of their generics-only market definition and reviewed the Plaintiffs' evidence of Coumadin and Barr pricing, inelastic demand (i.e., consumer unwillingness to purchase generic warfarin sodium), different distribution chains, industry recognition and supply substitution. Id. at 496-99. After reviewing that evidence, it concluded: "We therefore hold that the relevant market for our purposes is the market for generic warfarin sodium tablets." Id. at 500.

The Court of Appeals proceeded to review the other elements of the Section 2 claims regarding warfarin sodium tablets and concluded that there is a question of material fact regarding Barr's monopoly power, id. at 501, and the willful acquisition or maintenance of monopoly power, id. at 504-05. It then remanded the case as follows:

> Accordingly, for the foregoing reasons, we (1) reverse the grant of summary judgment dismissing all plaintiffs' claims brought pursuant to the Sherman Act §§ 1 and 2; (2) affirm the dismissal of the Clayton Act claim; and (3) reverse the ruling that plaintiff Apothecon lacks standing to sue. The case is remanded to the district court for further proceedings consistent with this opinion.

Id. at 514.

The Defendants filed a motion for clarification or, in the alternative, petition for partial rehearing to clarify what the Court of Appeals intended with its "hold[ing] that the relevant market for our purposes is the market for generic warfarin sodium tablets." Id. at 500. Defendants asked the Court of Appeals to clarify its decision because:

> While the posture of the case, the evidence before the Court, and the Opinion itself strongly suggest that the definition of the relevant market is reserved for trial, it is unclear whether this Court meant to (1) remand this case for trial on the issue of market definition or (2) rule as a matter of law that the relevant market is limited to generic warfarin sodium tablets and does not include the brand, Coumadin.

The Court of Appeals denied the Defendants' motion without explanation or opinion on December 16, 2004.

On August 9, 2005, these cases were transferred to this Court. At a conference on August 23, the Court advised the

parties that the Defendants' motion to determine the scope of the remand was granted, that the issue of the market definition would be submitted to a jury, and set a schedule for the completion of discovery and a trial date of June 12, 2006. This Opinion explains in greater detail the reasons for that ruling on the Defendants' motions.

DISCUSSION

The Scope Of The Remand

It is an unaccustomed task for the district court to determine the scope of the remand. The guide for the performance of this delicate task is the doctrine known as the mandate rule, which dictates a careful examination of both the remand order itself and the "broader spirit" of the remand. The Second Circuit has described the mandate rule as follows:

> The mandate rule compels compliance on remand with the dictates of the superior court and forecloses relitigation of issues expressly or impliedly decided by the appellate court. Likewise, where an issue was ripe for review at the time of an initial appeal but was nonetheless foregone, the mandate rule generally prohibits the district court from reopening the issue on remand unless the mandate can reasonably be understood as permitting it to do so.
>
> To determine whether an issue remains open for reconsideration on remand, the trial court should look to both the specific dictates of the remand order as well as the broader spirit of the mandate.

United States v. Ben Zvi, 242 F.3d 89, 95 (2d Cir. 2001) (citation omitted) (emphasis in original). See also Landell v. Sorrell, 382 F.3d 91, 136 n.25 (2d Cir. 2004).

The task before the Court of Appeals was the propriety of the grant of summary judgment, construing all facts in favor of the Plaintiffs. Given the procedural posture of the appeal, by necessity, the Court of Appeals decided only the question of whether the facts supported summary judgment for the Defendants. According to the Court of Appeals, they did not. The remand therefore must be read to include fact-finding as to the market definition. Any other conclusion would constitute a grant of summary judgment in the Plaintiffs' favor by the Court of Appeals on a hotly contested issue. Since Plaintiffs never sought summary judgment on this or any aspect of their claims, such a result would be at odds with the standards customarily applied on appeal and specifically enunciated in the October 18 Opinion.

When the Court of Appeals has chosen to grant summary judgment, it has been explicit in doing so. See, e.g., Mut. Export Corp. v. Westpac Banking Corp., 983 F.2d 420, 424 (2d Cir. 1993) ("Accordingly, we reverse the judgment of the district court, with directions to grant Westpac's motion for summary judgment."); Vives v. City of New York, 393 F.3d 129, 133 (2d Cir. 2004) ("[T]he cause is remanded to the District Court with instructions to enter summary judgment in favor of defendants . . . ."). There is no parallel explicit grant of summary judgment here.[1]

[1] The cases cited by Plaintiffs highlight that the October 18 Opinion lacks any limiting instructions of the type included by the Appellate Court when it intends to restrict proceedings following remand. See Ginett v. Computer Task Group, Inc., 11

Reinforcing the conclusion that the issue of the market definition was remanded for trial is the repeated reference by the Court of Appeals to the standard of review it applied to the facts: "Upon reviewing the record, we draw all inferences and resolve all ambiguities in favor of the non-moving party, here plaintiffs." Geneva, 386 F.3d at 495. The Court of Appeals acknowledged that it examined the evidence "[w]ith these standards in mind." Id. "[T]hese standards," are the standards applied to determine if fact questions exist, not to resolve fact questions.

In the context of the task the Court of Appeals performed, that is, the reversal of a grant of summary judgment, its observations concerning the relevant market must be understood as recognition that the plaintiffs had sufficient evidence in the record to support a verdict, and therefore, to require a trial. This conclusion is reinforced by the acknowledgment of the Court of Appeals that key facts regarding market definition were in dispute. For example, the Court of Appeals cited the Plaintiffs' evidence that Barr allegedly dropped its prices when Geneva entered the market as evidence that supported a generics-only relevant market definition. Id. at 497; see also id. at 500. ("Barr's price was impacted much more by Geneva's entry than by Coumadin."). On the other hand, the Court of Appeals noted that

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F.3d 359, 360-61 (2d Cir. 1993); Ginett v. Computer Task Group, Inc., 962 F.2d 1085, 1101 (2d Cir. 1992); Day v. Morgenthau, 909 F.2d 75, 78 (2d Cir. 1990).

direct evidence that Barr lowered prices in response to Geneva's entry was "at best ambiguous," id. at 500, and "somewhat inconclusive," id. at 509. Similarly, the Court of Appeals considered "supply substitution" in analyzing the relevant market, id. at 499, and "readily" dismissed the possibility that other generic manufacturers could enter the market because of "high barriers to entry resulting . . . from limited supply of clathrate." Id. Yet, when it actually surveyed the conflicting evidence regarding the availability of clathrate suppliers, the Court of Appeals ruled that there is "a factual dispute over the availability of clathrate." Id. at 504; see also id. at 502 (concluding that there was a factual dispute over whether ACIC/Brantford was the only supplier of available clathrate). Reading the Court of Appeal's analysis of relevant market in conjunction with its finding that key facts are "ambiguous," "inconclusive" and "disputed" leads ineluctably to the conclusion that the Court of Appeals sought to search for fact issues, not resolve them.

Based on the factors just discussed, the Defendants' motion to determine the scope of the remand is granted. Relying on both the specific dictates of the remand order and the broader spirit of the remand, it is abundantly clear that the Court of Appeals did not enter judgment in Plaintiffs' favor on the issue of the market definition. The trial will include the determination of the relevant market.

Additional Discovery

In a related application, Defendants seek to reopen discovery to explore marketplace conditions and other relevant events from the intervening months since discovery was closed. Based on the evidence submitted by the Defendants it appears that material events have occurred since the last discovery period, which justice requires that the parties have an opportunity to develop through discovery. Several of the legal issues to which these more recent events are relevant are described here.

The Defendants have submitted new market evidence in support of their motion that is highly relevant to an analysis of the structure of the warfarin sodium market and the willingness of consumers to choose the generic over the brand drug. The data in the record before the Court of Appeals reflected 68% of all warfarin sodium sales going to Coumadin and 32% to the generics. After looking at the data regarding generic market penetration created by the record on appeal, the Court of Appeals "concluded" that Coumadin customers "clearly do not perceive generics to be a reasonable substitute for it." Geneva, 386 F.3d at 497. It would appear that the appellate court also concluded that the perceived consumer unwillingness to switch was a "trend" that would continue. See id. at 498.

The new data submitted on this motion shows virtually the opposite; 38% of warfarin sodium sales are of Coumadin while 62% are of generics. This new evidence strongly suggests that Coumadin customers have not remained loyal to Coumadin and are

willing to switch to generic warfarin sodium, and that demand for the branded drug is not inelastic. Indeed, the new market data appears to indicate that the actual trend reflects a high willingness of consumers to switch. See AD/SAT, Div. of Skylight, Inc. v. Associated Press, 181 F.3d 216, 227 (2d Cir. 1999) ("Cross-elasticity of demand exists if consumers would respond to a slight increase in the price of one product by switching to another product."). See also Lektro-Vend Corp. v. Vendo Co., 660 F.2d 255, 270-71 (7th Cir. 1982) (market performance subsequent to alleged attempt to monopolize is relevant to Section 2 claim); Nifty Foods Corp. v. Great Atl. & Pac. Tea Co., 614 F.2d 832, 841 (2d Cir. 1980) (dismissing Section 2 claim based on market share evidence subsequent to alleged conduct).

The Defendants have also presented new, relevant evidence regarding the barriers to entry. When analyzing the relevant market, the Court of Appeals found that there was no possibility of supply substitution:

> We can readily dismiss potential substitution from all entities other than DuPont. We find evidence of particularly high barriers to entry resulting both from limited supply of clathrate and from the regulatory requirements to sell generics. We find no evidence that other generic pharmaceutical manufacturers could quickly and easily have entered the warfarin market if generic warfarin prices were raised substantially above marginal cost.

Geneva, 386 F.3d at 499. Taro had just entered the market at the time discovery was closed and had such a small share (3%) that it did not even rate a mention as an entrant to the marketplace.

The new market data shows that Taro has successfully penetrated the market, gaining 19% of overall warfarin sales and 31% of generic warfarin sales. USL Laboratories and Genpharm also have recently entered the marketplace.

The Plaintiffs have urged that the entry of USL Laboratories in 2003 and Genpharm in 2004 "can be easily dismissed as irrelevant" because their entry occurred "five or more years after Plaintiffs' entry and Defendants' unlawful conduct which delayed Plaintiffs' entry." The time period for analyzing the ability of a competitor to enter the marketplace, however, is not tied to the date of a defendant's alleged unlawful conduct. "Of course, some time may pass between the commencement of monopoly pricing and a firm's decision to enter." Areeda & Hovenkamp, ¶ 422b, at 77. "[E]stimating the time required for entry is itself very rough" and should start with "initial planning after one decides to enter." Id. Potential entrants in a market must be considered in the relevant market analysis. See United States v. Falstaff Brewing Corp., 410 U.S. 526, 532-34 (1973) (discussing the influence of potential entrants on existing competition in the relevant market). The entrance of USL Laboratories and Genpharm suggests that it may be appropriate to consider them as potential entrants prior to their actual entry date.

Furthermore, the Plaintiffs claim damages of up to $190.8 million, which would be trebled under the antitrust laws and, according to Plaintiffs, adjusted further for interest. The Plaintiffs base their damages calculation on lost warfarin sales

from 1997 through 2010. Plaintiffs' expert reports previously were based on actual data through 1999 or 2000 and assumptions, projections, and hypotheses for subsequent years, which related to, inter alia, an assumed conversion rate of sales of the Coumadin brand to generics; assumed patterns of price increases of the Coumadin brand; assumed price and sales data at which Apothecon would sell its warfarin sodium product; and Apothecon's assumed success in the marketplace.

As discussed above, new companies have entered, the marketplace positions of competitors have changed, and new sales patterns have developed. In addition, Geneva has purchased Invamed and Apothecon's product rights to sell warfarin sodium. Invamed and Apothecon are out of the warfarin sodium business and the alleged Invamed/Apothecon joint venture (which is at the core of the damage calculations) has dissolved. BMS, the parent of Apothecon, has purchased the Coumadin brand. In addition, current IMS data shows that since July 2003 Geneva apparently has stopped actively selling warfarin sodium and currently has essentially a 0% market share. Publicly available data does not explain why Geneva exited this market. To evaluate damages, the parties are entitled to discovery regarding each of these events so that any damages award can be based on the firmest possible factual record.

As a final example, the conduct and success of new entrants (as well as Taro) is relevant to causation. For example, Defendants should be entitled to investigate whether Plaintiffs'

lack of success in the marketplace was due to their own marketing and pricing decisions, and not due to Defendants' alleged anticompetitive conduct.

As these examples demonstrate, there has been a significant alteration in the marketplace while this case has been proceeding through summary judgment practice, an appeal, and motion practice on remand. Fairness requires that the parties have an opportunity to explore the new environment through discovery so that any verdict that a jury returns reflects as closely as possible the realities of the marketplace.

CONCLUSION

The trial on Plaintiffs' Section 2 claims should proceed on all issues, including relevant market definition. Discovery has been reopened to allow the parties to gather evidence for the entire relevant period up to and including the present.

SO ORDERED:

Dated: New York, New York
September 6, 2005

DENISE COTE
United States District Judge